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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,720	07/24/2001	James P. Hearn	8932-177	1799

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3732

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/910,720

Applicant(s)

HEARN ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-16,27,29-39,41,43-46,49-54,58,59,64,65,67,72,73 and 75-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5-10,27,29-39,41,43-46,49-54,58,59,64,65,67,72,73,86 and 87 is/are allowed.
- 6) ☒ Claim(s) 11-13, 15-16, 75-76 and 81-85 is/are rejected.
- 7) ☒ Claim(s) 14 and 77-80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 11, 15, 75 and 81-85, are rejected under 35 U.S.C. 102(e) as being anticipated by Herrington et al. (US 6,379,363).

Herrington et al. disclose a cranial clamp having a smooth base or first clamping member 12, a head 30 disposed proximate first clamping member with a bore, a stem or “integral extension member” or “tube” 16 placed in the bore of head 30, a smooth cap or second clamping member 14 and an “integrally formed stop member” or “crimp” or “ridge” or “twisted portion” or “proximal flared portion” 34 which limits the movement of clamping member 14 on extension member 16 (Figures 1 and 21e, col. 4, lines 4-67 and col. 5, lines 5-31).

Regarding claim 11, Herrington et al. further disclose second clamping member to have radial cutouts defining protrusions 52 extending inwardly from an outer circumference of clamping member 14 (col. 4, lines 59-67, col. 5, lines 1-17 and Attachment A of the Office Action mailed on October 4, 2004).

Regarding claim 75, the method by which an apparatus is made, “provided by mechanical deformation of the extension member” is not given any patentable weight in an apparatus claim (*In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)).

Regarding claim 83, opening 59 includes a countersink or an “enlarged opening” defined by bores 60 (Figures 1 and 3).

Regarding claim 84, second clamping member 14 has a recessed area 38 proximate or “very near” circular opening 59 receiving stop 32 (Figure 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 15-16, 75-76 and 81-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrington et al.

See previous discussion of Herrington et al.

Herrington et al. disclose that clamp 10 could be formed of any biocompatible material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the clamp of a resilient material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It is the Examiner's position that the extent of flattening of clamping member 14 is dependent on the material that the clamping member is made of. A more resilient material would flatten more than a less resilient material.

Regarding claims 12 and 76, although Herrington et al. do not disclose that extension member 16 is a ribbon or a longitudinal member with a rectangular cross section, it would have been obvious to one of ordinary skill in the art to substitute a ribbon for the extension member wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art, namely a structure capable of being sheared off against a suitable surface, and the selection of any of these structures would work equally well in the claimed device.

Regarding claim 13, second clamping member 14 of Herrington et al. has a recessed area 38 surrounding opening 59 that receives stop 32 (Figure 1).

Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a fastener hole in second

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clamping member for securing the clamping member since it is well known in the art to utilize fasteners for the purpose of securing one member to another.

Regarding claim 75, the method by which an apparatus is made, "provided by mechanical deformation of the extension member" is not given any patentable weight in an apparatus claim (*In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972)).

Regarding claim 83, opening 59 includes a countersink or an "enlarged opening" defined by the cutouts (Figures 1 and 3).

Regarding claim 84, second clamping member 14 has a recessed area 38 proximate or "very near" circular opening 59 receiving stop 32 (Figure 1).

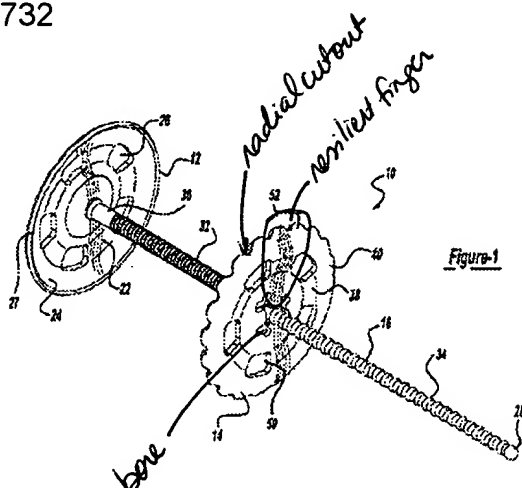
### ***Response to Arguments***

Applicant's arguments under "REMARKS" submitted in the response filed on January 3, 2005, with respect to independent claim 11 have been considered but are not persuasive for the following reasons.

With regard to claim 11, Herrington et al. disclose radial cutouts (see Attachment A) of the office action mailed on October 4, 2004.

Regarding the limitation, "so that movement of the clamping member.....flatten out allowing the clamping member to at least partially conform to the outer surface of the bone flap and skull, Herrington et al. disclose that second clamping member 14 has resilient fingers defined by radial cutouts and bores 60 which will cause the clamping member to at least partially conform to the outer surface of the skull (col. 4, lines 59-67 and col. 5, lines 1-17). See marked up Figure 1 on the following page.

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### ***Allowable Subject Matter***

Claims 1-2, 5-10, 27, 29-39, 41, 43-46, 49-54, 58-59, 64-65, 67, 72-73 and 86-87 are allowed.

Claims 14 and 77-80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuradha Ramana*  
March 11, 2005

*Kevin Shaver*  
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